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सत्यमेव जयते

INTELLECTUAL PROPERTY INDIA

GOVERNMENT OF INDIA
MINISTRY OF COMMERCE & INDUSTRY,
PATENT OFFICE, DELHI BRANCH,
W - 5, WEST PATEL NAGAR,
NEW DELHI - 110 008.

IB/04/1104

*I, the undersigned being an officer duly authorized in accordance with the provision of the Patent Act, 1970 hereby certify that annexed hereto is the true copy of the* ***Application*** *and* ***Complete Specification*** *filed in connection with Application for Patent No.* ***591/Del/03*** *dated* ***09th April 2003.***

*Witness my hand this 17th day of May 2004.*

*(S.K. PANGASA)*
*Assistant Controller of Patents & Designs*

**PRIORITY DOCUMENT**
SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

0591-DEL-03

Drug/Biochem

A61K 31/00 ; A61K9/20

09 APR 2003

Govt. of India Patent Office New Delhi Received Rs. 5000/- in cash. Che ue/M.O /I.P.O./D.D. on 09 APR 2003 Vide Entry No. 4269 in the Register of Valuables 4.0 ..... Cashier

**FORM 1**

**THE PATENTS ACT, 1970**

(39 of 1970)

# APPLICATION FOR GRANT OF A PATENT

**(See Sections 7, 54 and 135 and rule 33A)**

1 We, **RANBAXY LABORATORIES LIMITED**, a Company incorporated under the Companies Act, 1956 of 19, Nehru Place, New Delhi - 110 019, India

2. hereby declare –

(a) that we are in possession of an invention titled **"A PROCESS FOR THE PREPARATION OF WATER-SOLUBLE TABLET"**

(b) that the Complete Specification relating to this invention is filed with this application.

(c) that there is no lawful ground of objection to the grant of a patent to us.

3. Further declare that the inventors for the said invention are

a. DEEPAK MURPANI

b. ASHISH MADAN

c. SANJEEV SETHI

d. RAJIV MALIK

of Ranbaxy Laboratories Limited, Plot No. 20, Sector-18, Udyog Vihar Industrial Area, Gurgaon – 122001 (Haryana), India, all Indian Nationals.

4. That we are the assignee or legal representatives of the true and first inventors.

5. That our address for service in India is as follows:

**DR. B. VIJAYARAGHAVAN**
**Associate Director – Intellectual Property**
Ranbaxy Laboratories Limited
Plot No.20, Sector – 18,
Udyog Vihar Industrial Area,
Gurgaon – 122001 (Haryana).
INDIA.
Tel. No. (91-124) 2343126, 2342001 – 10; 5012501-10
Fax No. (91-124) 2342027 ; 2343545

6. Following declaration was given by the inventors in the convention country:

We, DEEPAK MURPANI, ASHISH MADAN, SANJEEV SETHI, RAJIV MALIK of Ranbaxy Laboratories Limited, Plot No. 20, Sector – 18, Udyog Vihar Industrial Area, Gurgaon–122001 (Haryana), India, all Indian Nationals, the true and first inventors for this invention in the convention country declare that the applicants herein, **Ranbaxy Laboratories Limited**, 19, Nehru Place, New Delhi - 110 019, India, is our assignee or legal representatives.

a. Deepak Murpani
(DEEPAK MURPANI)

b.
(ASHISH MADAN)

c.
(SANJEEV SETHI)

d.
(RAJIV MALIK)

7. That to the best of our knowledge, information and belief the fact and matters stated herein are correct and that there is no lawful ground of objection to the grant of patent to us on this application.

8. Followings are the attachment with the application:

a. Complete Specification (3 copies)
b. Drawings (3 copies)
c. Statement and Undertaking on FORM – 3
d. Fee Rs.5,000/- (Rupees Five Thousand only..) in cheque bearing No. **688727**
dated :**25.03.2003** on **ANZ Grindlays Bank, New Delhi.**

We request that a patent may be granted to us for the said invention.

Dated this 9TH day of **April, 2003.**

**For Ranbaxy Laboratories Limited**

Sen

**(SUSHIL KUMAR PATAWARI)**
**COMPANY SECRETARY**

FORM 2 0591-03

09 APR 2003

The Patents Act, 1970

(39 of 1970)

## COMPLETE SPECIFICATION

(See Section 10)

# A PROCESS FOR THE PREPARATION OF WATER-SOLUBLE TABLET

RANBAXY LABORATORIES LIMITED
19, NEHRU PLACE, NEW DELHI - 110019

*A Company incorporated under the Companies Act, 1956.*

The following specification particularly describes and ascertains the nature of this invention and the manner in which it is to be performed:

The present invention relates to a process for the preparation of a water-soluble tablet, which dissolves to form a clear aqueous solution.

It has been observed that patient compliance is drastically reduced due to the inconvenience caused in swallowing the conventional dosage forms. Some of the dosage forms available are too large to be swallowed by elderly or children and in many cases; the patient's ability to swallow anything is compromised. Currently available dosage forms directed to resolve the issue of convenience while medicating such patients are dispersible tablets, effervescent tablets and mouth dissolving tablets.

The dispersible tablets are dispersed in water prior to dosing and suspension so formed is consumed. The suspension may be convenient but it gives a feeling of grittiness in the mouth due to presence of water insoluble excipients such as disintegrants. Moreover, there is a possibility of dose loss because the active ingredient may get trapped in these insoluble excipients.

The other choice available is effervescent tablet, which in addition to the problems associated with dispersible tablets, have the problem of stability. These dosage forms contain an acid/base couple to produce effervescence. In presence of water these ingredients react to produce carbon dioxide and thus effervescence. During the process of manufacture, care is to be taken to avoid contact with moisture. It requires special manufacturing facility in order to maintain conditions of low relative humidity and low temperatures, which increases cost and overheads. When the dosage form is formed, it requires special packaging means to avoid any moisture absorption during storage. Consequently, these requirements make the manufacturing of effervescent dosage forms a complicated choice.

US Pat. No. 3692896 describes the preparation of water-soluble tablet by direct compression wherein the tablet comprises water-soluble active, lactose and micronized polyethylene glycol as lubricant. Lactose undergo Malliard reaction in presence of free amines and also results in slow disintegration of the tablet.

Most of the active ingredients have unacceptable taste that becomes more prominent when given in solution form.

We have surprisingly discovered that tablet having pleasant taste and capable of dissolving within 3 minutes in water without residual particulate matter can be easily prepared by use of water soluble sugar alcohols in place of saccharides. The sugar alcohols such as sorbitol, mannitol, xylitol, isomalt and hydrogenated starch hydrolysates not only help in quick disintegration of the tablet but also provide compressible properties to the bulk. Mannitol is nonhygroscopic. It does not add moisture or contribute to moisture pickup. It is also chemically inert. These properties make mannitol a useful excipient for tablets because it protects water-sensitive active ingredients from degradation and does not react with the active ingredient. Mannitol does not undergo the Maillard reaction and therefore does not discolor in the presence of free amines. Therefore water-soluble tablet can be prepared by compression of water-soluble active ingredient with water-soluble sugar alcohols and water-soluble lubricant.

The process is simple and suitable for a broad range of active ingredients with different physico-chemical parameters and tablets can comprise a high dose of the active medicament.

The process provides tablets, which are rapidly soluble in aqueous media and provide an easy mode of administration. These tablets may also be swallowed as other conventional tablets.

The tablet has sufficient hardness and friability to withstand impacts during manufacturing, packaging and transport.

Therefore in one general aspect it provides a water-soluble tablet capable of dissolving within 3 minutes, in particular in 2 minutes and more particularly in 1 minute in about 30 ml, in particular about 20 ml and more particularly in about 15 ml water to give clear solution.

In another general aspect it provides a water-soluble tablet having hardness of about 2 kP to about 8 kP and capable of dissolving within 3 minutes, in particular in about 2 minutes and more particularly in about 1 minute in about 30 ml, in particular about 20 ml and more particularly in about 15 ml water to form a clear solution.

In another general aspect it provides a water-soluble tablet having pleasant taste.

In another general aspect it provides a water-soluble tablet capable of dissolving within 3 minutes, in particular in 2 minutes and more particularly in 1 minute in about 30 ml, in particular about 20 ml and more particularly in about 15 ml water to give clear solution, comprising water-soluble active ingredients, water-soluble sugar alcohols and water-soluble lubricant.

In another general aspect it provides a water-soluble tablet capable of dissolving within 3 minutes, in particular in 2 minutes and more particularly in 1 minute in about 30 ml, in particular about 20 ml and more particularly in about 15 ml water to give clear solution, comprising water-soluble active ingredients, xylitol, mannitol and water-soluble lubricant.

In another general aspect it provides a process for the preparation of water-soluble tablet capable of dissolving within 3 minutes, in particular in 2 minutes and more particularly in 1 minute in about 30 ml, in particular about 20 ml and more particularly in about 15 ml water to give clear solution.

In another general aspect it provides a process for the preparation of water-soluble tablet having hardness of about 2 kP to about 8 kP and capable of dissolving within 3 minutes, in particular in about 2 minutes and more particularly in about 1 minute in about 30 ml, in particular about 20 ml and more particularly in about 15 ml water to form a clear solution.

In another general aspect it provides a process for the preparation of water-soluble tablet having pleasant taste.

In another general aspect it provides a process for the preparation of water-soluble tablet which comprises direct compression of a blend of water-soluble active ingredients with water-soluble sugar alcohols and water-soluble lubricant; and dissolves within 3 minutes, in particular in 2 minutes and more particularly in 1 minute in about 30 ml, in particular about 20 ml and more particularly in about 15 ml water to give clear solution.

In another general aspect it provides a process for the preparation of water-soluble tablet which comprises direct compression of a blend of water-soluble active

ingredients with xylitol, spray dried mannitol and water-soluble lubricant; and dissolves within 3 minutes in about 30 ml, in particular about 20 ml and more particularly in about 15 ml water to give clear solution.

In another general aspect it provides a process for the preparation of water-soluble tablet which comprises wet granulating a mixture of water-soluble active ingredients binder, water-soluble sugar alcohols and water-soluble lubricant; and dissolves within 3 minutes, in particular in 2 minutes and more particularly in 1 minute in about 30 ml, in particular about 20 ml and more particularly in about 15 ml water to give clear solution.

In another general aspect it provides a process for the preparation of water-soluble tablet which comprises wet granulating a mixture of water-soluble active ingredients, binder, xylitol, spray dried mannitol and water-soluble lubricant; and dissolves within 3 minutes in about 30 ml, in particular about 20 ml and more particularly in about 15 ml water to give clear solution.

In another general aspect it provides a process for the preparation of water-soluble tablet which comprises dry granulation by slugging or compaction of a mixture of water-soluble active ingredient, binder, water-soluble sugar alcohols and water-soluble lubricant; and dissolves within 3 minutes, in particular in 2 minutes and more particularly in 1 minute in about 30 ml, in particular about 20 ml and more particularly in about 15 ml water to give clear solution.

In another general aspect it provides a process for the preparation of water-soluble tablet which comprises dry granulation by slugging or compaction of a mixture of water-soluble active ingredients, binder, xylitol, spray dried mannitol and water-soluble lubricant; and dissolves within 3 minutes in about 30 ml, in particular about 20 ml and more particularly in about 15 ml water to give clear solution.

The term "water-soluble tablet" herein means as described in British Pharmacopoeia 1988, Vol II, an uncoated tablets that dissolve in water and the solution produced may be slightly opalescent due to added substances used in the manufacture of the tablets.

The term "water-soluble active ingredient" herein means an active ingredient having solubility of about at least 1 part in 30 parts of water. It also includes those active ingredients wherein 1 part of an active ingredient dissolves in more than 30 parts of

water, but under acidic or alkaline conditions, the solubility is increased upto 1 in 30 parts of water. The term "water-soluble active ingredient" also includes that active ingredient the therapeutic unit dose of which dissolves in about 30ml, in particular about 20ml and more particularly in about 15ml water in acidic, alkaline or neutral pH to give clear solution. The pH adjustment can be done using acidic or basic pharmaceutical excipients.

The term "clear aqueous solution" herein means the solution formed after the tablet has completely dissolved should appear transparent to the naked eye. However, the solution produced may be opalescent due to some water-insoluble impurities present in added excipients.

The water-soluble active ingredients for example, although not limiting to, can be metformin hydrochloride, gabapentin, glipizide, glibenclamide, diltiazem hydrochloride, verapamil hydrochloride, bupropion hydrochloride, propranolol hydrochloride, dextromethorphan hydrobromide, diphenhydramine hydrochloride, disopyramide hydrochloride, tramadol, fluoxetine hydrochloride, paroxetine hydrochloride, pentoxifylline hydrochloride, diclofenac sodium and the like. The water-soluble active ingredient may comprise up to about 95% weight by weight of the tablet.

The water-soluble sugar alcohols for example may be selected from sorbitol, mannitol, spray-dried mannitol, xylitol, erythritol isomalt and hydrogenated starch hydrolysates and combinations thereof. Particularly suitable are xylitol and spray dried mannitol. Mannitol can be spray-dried mannitol, which is available under the trade name Pearlitol. It is a free flowing directly compressible sugar and has cooling taste due to negative heat of solution. It gives tablets of good hardness and also facilitates quick dissolution. Spray Dried Mannitol has a particle shape that allows it to be free-flowing and easily mixed with other ingredients. These properties enable it to be used with high dose actives that may exhibit flow problems. Mixing these difficult to compress ingredients with spray-dried Mannitol makes it possible to formulate an elegant tablet. The sugar alcohol may comprise from about 10% to about 95% weight by weight of the tablet. In particular it may be present in about 30% to about 70% weight by weight of the tablet.
The water-soluble lubricant may be selected from DL-leucine, sodium lauryl sulphate, magnesium lauryl sulphate and polyethylene glycol. Particularly suitable is pulverized /micronised polyethylene glycol with 90% of the particles having size less than 250μm and have molecular weight from about 1500 to about 20,000, more particularly suitable

polyethylene glycols are those having molecular weights from about 3500 to about 8000. The water-soluble lubricant may comprise from about 0.1% to about 10% weight by weight, particularly from about 2% to about 10% weight by weight of the tablet.

Besides the active ingredient, water-soluble sugar alcohol(s) and water-soluble lubricant, the tablet may comprise of binders, pH modifiers, sweeteners and flavouring agents.

The binder may be selected from soluble starch, polyvinylpyrrolidone, cellulose ethers, gums, carboxyvinyl polymer(s) or combinations thereof.

The pH modifier may be selected from potassium hydroxide, sodium hydroxide, monosodium citrate, citric acid and the like.
The sweetener may be selected from aspartame, saccharine sodium, glycine, lactose, dextrose, fructose, maltose, sorbitol and sucrose, particularly aspartame.

The flavouring agents may be selected from strawberry aroma, raspberry aroma, cherry flavour, lime flavour, fruit extracts, citrates and tartarates.

The tablet can be prepared by any conventional tableting method. In direct compression method, the water-soluble active ingredient, sugar alcohol(s), water-soluble lubricant and other optional water-soluble excipients may be sifted through a mesh of suitable size. The sifted blend may be mixed with water-soluble lubricant and compressed using suitable tooling.

In wet granulation method, the active ingredient may be mixed with a binder and granulated with purified water. Alternatively, the water-soluble active ingredient may be mixed with sugar alcohol(s) and optionally water-soluble lubricant and granulated with a binder solution. The granules can be dried and mixed with other excipient(s), water-soluble lubricant and compressed using suitable tooling.

In dry granulation the blend of all the ingredients can be compacted to make granules of suitable size and mixed with water-soluble lubricant and compressed.

Tablet in particular is the final dosage form, however granules comprising the water-soluble active ingredient and water-soluble sugar alcohols, water-soluble lubricant and

other optional excipients can also be prepared and packed into sachets, bottles or other suitable packaging devices meant for unit/multiple dosage. These granules can be dissolved in water to give a clear solution and consumed.

The following examples are given for purpose of illustrating the present invention and not intended to limit the scope in any way.

**Example 1**

The tablets of example 1 were formulated with a water-soluble-active ingredient, metformin hydrochloride (500mg); sugar alcohol(s), spray-dried mannitol (200mg), xylitol (200mg); sweetener, aspartame (45mg); flavoring agent, monosodium citrate (20mg); and lubricant, micronized polyethylene glycol (25). Metformin, spray-dried mannitol, xylitol, aspartame and monosodium citrate (20mg) were sifted through a suitable mesh. The micronized polyethylene glycol was mixed with the above sifted blend and compressed into a tablet using appropriate tooling. The tablets thus obtained when dropped in 30 ml of water, dissolved quickly to give a clear solution.

**Example 2**

The tablets of example 2 were formulated with a water-soluble active ingredient, metformin hydrochloride (500mg); binder, polyvinyl pyrrolidone, (10mg); sugar alcohol(s), spray-dried mannitol (200mg), xylitol (200mg); sweetener, aspartame (45mg); flavoring agent, monosodium citrate (20mg); and lubricant, micronized polyethylene glycol (25 mg). The metformin hydrochloride and polyvinyl pyrrolidone were mixed in a blender and granulated with purified water. The granules were dried and mixed with spray-dried mannitol, xylitol, aspartame and monosodium citrate. The above blend was then mixed with the micronized polyethylene glycol and compressed using appropriate tooling. The tablets thus obtained when dropped in 30 ml of water, dissolved quickly to give a clear solution.

The compositions of example 1-2, prepared using metformin hydrochloride as the water-soluble active ingredient are listed in Table 1.

**Table 1: Water-soluble tablets of Metformin hydrochloride**

| Composition | Example 1 | Example 2 |
|---|---|---|
| Metformin hydrochloride | 500mg | 500mg |
| Polyvinylpyrrolidone | -- | 10mg |
| Xylitol | 200mg | 200mg |
| Mannitol (spray-dried) | 200mg | 200mg |
| Aspartame | 45mg | 45mg |
| Monosodium citrate | 20mg | 20mg |
| Polyethylene glycol | 25mg | 25mg |
| Purified water | q.s. | q.s. |
| **Total weight** | **990mg** | **1000mg** |

While several particular formulations have been described above, it will be apparent that various modifications and combinations of the formulation detailec in the text can be made without departing from the spirit and scope of the invention. For example, additional exemplary tablet formulations are contemplated to use the water-soluble sugar alcohols described above and the water-soluble excipients. Water-soluble tablets of gabapentin and metformin hydrochloride+ glibenclamide combinations can be prepared as disclosed in Tables 2 – 3 (Examples 3-5).

**Table 2: Water-soluble tablets of Gabapentin**

| Composition | Example 3 | Example 4 |
|---|---|---|
| Gabapentin | 600mg | 600mg |
| Polyvinylpyrrolidone | -- | 10mg |
| Xylitol | 200mg | 200mg |
| Mannitol (spray-dried) | 200mg | 200mg |
| Aspartame | 45mg | 45mg |
| Monosodium citrate | 20mg | 20mg |
| Polyethylene glycol | 25mg | 25mg |
| Purified water | | q.s. |
| **Total weight** | **1090mg** | **1080mg** |

**Table 3: Water-soluble tablets of Metformin hydrochloride+Glibenclamide combination**

Glibenclamide has poor solubility in neutral or acidic pH. Water-soluble tablets containing metformin hydrochloride and glibenclamide comprising an alkali such as

sodium hydroxide were prepared and when the tablet dropped in 30 ml of water dissolved quickly to give a clear solution.

| Composition | Example 5 |
|---|---|
| Metformin hydrochloride | 500mg |
| Glibenclamide | 5 mg |
| Polyvinylpyrrolidone | 10 mg |
| Xylitol | 200 mg |
| Sodium hydroxide | 5 mg |
| Mannitol (spray dried) | 170mg |
| Aspartame | 45mg |
| Saccharin sodium | 5 mg |
| Flavors | 30mg |
| Polyethylene glycol | 30mg |
| Purified water | q.s. |
| **Total weight** | **1000 mg** |

**WE CLAIM:**

1. A process for the preparation of a water-soluble tablet wherein the process comprises compressing a mixture of:
   (a) at least one water-soluble active ingredient;
   (b) water soluble sugar alcohol(s)
   (c) water-soluble lubricant; and
   which tablet dissolves in about 3 minutes in about 30 ml of water to give a clear solution.
2. The process according to claim 1 wherein the tablet dissolves in water within two minutes to give a clear solution.
3. The process according to claim 1 wherein the tablet dissolves in water within one minute to give a clear solution.
4. The process according to claim 1 wherein the tablet is dissolved in about 20 ml of water.
5. The process according to claim 1 wherein the tablet is dissolved in about 15 ml of water.
6. The process according to claim 1 wherein the mixture is formulated into a tablet by direct compression.
7. The process according to claim 1 wherein the mixture is granulated prior to compression.
8. The process according to claim 7 wherein the mixture is wet granulated.
9. The process according to claim 7 wherein the mixture is dry granulated.
10. The process according to claim 1 wherein the water-soluble active ingredient has a solubility of at least 1 part in 30 parts of water at neutral, acidic or alkaline pH.
11. The process according to claim 1 wherein the therapeutic unit dose of active ingredient is soluble in 30ml of water in acidic, alkaline or neutral pH.
12. The process according to claim 1 wherein the water-soluble active ingredient comprises not more than 95% weight by weight of the tablet.
13. The process according to claim 12 wherein water-soluble active ingredient is selected from metformin hydrochloride, gabapentin, glibenclamide, glipizide, diltiazem hydrochloride, verapamil hydrochloride, bupropion hydrochloride, propranolol hydrochloride, dextromethorphan hydrobromide, diphenhydramine hydrochloride, disopyramide hydrochloride, tramadol, fluoxetine hydrochloride, paroxetine hydrochloride, pentoxifylline hydrochloride, diclofenac sodium and the like.

14. The process according to claim 13 wherein the water-soluble active ingredient is metformin hydrochloride.
15. The process according to claim 13 wherein the water-soluble active ingredient is a combination of metformin hydrochloride and glibenclamide.
16. The process according to claim 13 wherein the water-soluble active ingredient is a combination of metformin hydrochloride and glipizide.
17. The process according to claim 13 wherein the active ingredient is gabapentin.
18. The process according to claim 1 wherein the sugar alcohol(s) is selected from sorbitol, mannitol, spray dried mannitol, xylitol, erythritol isomalt and hydrogenated starch hydrolysates and combinations thereof.
19. The process according to claim 14 wherein the sugar alcohol(s) is xylitol.
20. The process according to claim 14 wherein the sugar alcohol(s) is mannitol.
21. The process according to claim 14 wherein the sugar alcohol(s) is a mixture of xylitol and mannitol.
22. The process according to claim 1 wherein the water-soluble lubricant is selected from DL-leucine, sodium lauryl sulphate, magnesium lauryl sulphate and polyethylene glycol.
23. The process according to claim 22 wherein the lubricant is DL-leucine.
24. The process according to claim 22 wherein the lubricant is sodium lauryl sulphate.
25. The process according to claim 22 wherein the lubricant is magnesium lauryl sulphate.
26. The process according to claim 22 wherein the lubricant is pulverized/micronised polyethylene glycol.
27. The process according to claim 26 wherein the polyethylene glycol has particle size with 90% of the particles having size less than 250μm
28. The process according to claim 27 wherein the polyethylene glycol has molecular weight of form about 3500 to about 20,000.
29. The process according to claim 28 wherein the polyethylene glycol has molecular weight of from about 3500 to about 8000.
30. The process according to claim 29 wherein the polyethylene glycol has molecular weight of 6000.
31. The process according to claim 29 wherein the polyethylene glycol has molecular weight of 8000.
32. The process according to claim 1 wherein the tablet further comprises other pharmaceutical excipients.

33. The process according to claim 32 wherein the other pharmaceutical excipients include binders, pH modifiers, sweeteners, and flavouring agents.

34. The process according to claim 33 wherein the binder is selected from soluble starch, polyvinylpyrrolidone, cellulose ethers, gums and carboxyvinyl polymer(s).

35. The process according to claim 34 wherein the binder is polyvinylpyrrolidone.

36. The process according to claim 33 wherein the pH modifier is selected from potassium hydroxide, sodium hydroxide, monosodium citrate, citric acid and the like.

37. The process according to claim 36 wherein the pH modifier is potassium hydroxide.

38. The process according to claim 36 wherein the pH modifier is sodium hydroxide.

39. The process according to claim 36 wherein the pH modifier is monosodium citrate.

40. The process according to claim 36 wherein the pH modifier is citric acid.

41. The process according to claim 33 wherein the sweetener is selected from aspartame, saccharine sodium, glycine, lactose, dextrose, fructose, maltose, sorbitol and sucrose.

42. The process according to claim 41 wherein the sweetener is aspartame.

43. The process according to claim 1 wherein the tablet comprises water-soluble active ingredient, xylitol, spray-dried mannitol and micronized polyethylene glycol and which tablet dissolves in about 30ml of water within three minutes to give a clear solution.

44. A process for the preparation of a water-soluble tablet which comprises direct compression or wet granulation or dry granulation prior to compression, of a blend of water soluble active ingredient, sugar alcohol(s) and micronized polyethylene glycol substantially as described and illustrated by the examples herein.

Dated this 9TH day of **April, 2003.**

**For Ranbaxy Laboratories Limited**

**(Sushil Kumar Patawari)**
**Company Secretary**

## ABSTRACT

The present invention relates to a process for the preparation of a water-soluble tablet, which dissolves to form a clear aqueous solution having good palatability.